K01411

FEB 0 5 2002

SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number:

VasSol, Inc.
2201 Campbell Park Drive
Suite 2260
Chicago, IL 60612

Submission Correspondent:

Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, NJ 08822
Attention: Lynette Howard

Classification Name: Magnetic Resonance Diagnostic Device Accessory
Common / Usual Name: Neuro-Vascular Analysis Software for Diagnosis
Proprietary Name: CANVAS N-VAS-D 2.0

Establishment Registration Number: Pending

Classification: Class II, Reg. # 21 CFR 892.1000

Performance Standards: No performance standards have been developed for this device.

Devices to which we claim Substantial Equivalence:

GE Advantage Windows (K923077A) & GE "Magnetic Resonance Diagnostic Accessory" (K924605).

The intended use of the device to which we claim substantial equivalence:

The General Electric Flow Analysis Option (K924605) in intended to quantitatively measure flow from a vessel using the principles of NMR. The GE Medical Systems 3D option (K923077A) is intended to create images of the anatomy in three dimensions from a set of CT or MRI images. The Dentascan option is intended to create a cross-referenced set of correlated axial, panorex and oblique planar images of the mandible and maxilla from CT scans of the jaw.

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Testing conducted to assure safety and effectiveness include but is not limited to:

Software Verification and Validation including:

- **Software Installation**
- **Image Extraction and Transfer Test**
- **Product Validation**
- **Flow Velocity**
- **Flow Rate**
- **Perpendicularity of Vessel Cut**
- **ROI Repeatibility**
- **Image Orientation**
- **Data Integrity**
- **Function Testing**

Proposed device has successfully met the requirements of the above.

Description of the new device:

N-VAS-D is a software tool used to non-invasively measure blood flow in the vascular system. N-VAS-D works on the images acquired from an MRI. It uses Time-of-Flight MRI images obtained via digital network to generate a 3D image. N-VAS-D allows fast scan acquisition time, fast post processing, and accurate flow measurement. N-VAS-D provides accurate vessel identification y using stereo visualization. N-VAS-D gives velocity and volume flow as a function of time, and other derived data such as mean velocity and volumetric flow rate. N-VAS-D generates a web browser compatible flow report that shows both flow results and images.

The N-VAS-D 2.0 includes three modules: 3DP, 3DFLOW and AUTOREPORT. N-VAS-D works on the images acquired from an MRI. It uses Time-of-Flight MRI images obtained via digital network to generate a 3D image. N-VAS-D allows fast scan acquisition time, fast post processing, and accurate flow measurement. N-VAS-D provides accurate vessel identification by using stereo visualization. N-VAS-D gives velocity and volume flow as a function of time, and other derived data such as mean velocity and volumetric flow rate. N-VAS-D generates a web browser compatible flow report that shows both flow results and images.

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Intended Use:

N-VAS-D is designed and intended for use as a supporting tool to non-invasive assessment of the vascular system. Intended purposes are:

- **Supporting clinical diagnoses about the flow velocity and volume flow through the vascular system.**
- **Supporting subsequent clinical decision making purposes.**
- **Supporting clinical post-operation and follow-up evaluation about the flow velocity and volume flow throughout the vascular system.**
- **Supporting the use in the treatment planning using computer modeling of the vascular system.**

Caution: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

VasSol, Inc.
% Ms. Lynette Howard
Submission Correspondent
Lyle Howard Corporation
203 Main Street, PMB 166
FLEMINGTON NJ 08822

Re: K014011
Trade/Device Name: CANVAS N-VAS-D 2.0
(Neuro-Vascular Analysis Software for Diagnosis)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: December 3, 2001
Received: December 5, 2001

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATION FOR USE

510(k) Number:

Device Name: **CANVAS N-VAS-D 2.0**

Indications for Use:

N-VAS-D is designed and intended for use as a supporting tool to non-invasive assessment of the vascular system. Intended purposes are:

- **Supporting clinical diagnoses about the flow velocity and volume flow through the vascular system.**
- **Supporting subsequent clinical decision making purposes.**
- **Supporting clinical post-operation and follow-up evaluation about the flow velocity and volume flow throughout the vascular system.**
- **Supporting the use in the treatment planning using computer modeling of the vascular system.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K014011

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